510(k) Summary of Safety and Effectiveness

The following section is included as required by the Safe Medical Device Act (SMDA) of 1990.

Name: pfm Produkte für die Medizin AG
Address: Wankelstr. 60
50996 Cologne
Germany
CONTACT PERSON: Salvadore F. Palomares, RAC

JAN 2 4 2002

510(k) Summary of Safety and Effectiveness
This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K011783
Trade Name: Multi-Snare Set
Common Name: Embolectomy Catheter
Classification Name: Same

Equivalent Devices:
Manufacturer: Microvena Corporation
Name: Microsnare
510(k) #: K925439
Manufacturer: Cook Inc.
Name: Welter Snare Retriever
510(k) #: K920823

Device Description:

The Multi-Snare Set is designed for the following indications:

- Retrieval and manipulation of foreign objects from the vascular system and hollow viscera
- Assistance in creating loops where cross-over-technique is applied
- Repositioning of indwelling venous catheters

The pfm Multi-Snare Set is contains of the following parts:

- Inner wire which forms the loop;
- Coil mounted on the inner wire in the loop section;
- Shaft body consisting of an outside coil and a core wire; and
- Transition from loop wire to shaft body.

The Multi-Snare Set consists of a highly elastic Nitinol wire with a pre-formed loop on its distal end. Because of the snare's highly elastic design, the snare can be introduced through an insertion sheath. The diameter of the snare can be adjusted depending on the position of the sheath. For better manipulation and torque-ability a torquer is provided.

The introducer sheath is designed for interventional insertion of instruments and systems into the vascular system.

The insertion sheath consists of polyethylene tubing, which is curved at its distal end and has a luer adapter at its proximal end. For better visualization the introducer sheath has an additional distal radiopaque marker.

Intended Use:
The Multi-Snare Set (and its components) is intended for:

- Retrieval and manipulation of foreign objects from the vascular system and hollow viscera
- Assistance in creating loops where cross-over technique is applied
- Repositioning of indwelling venous catheters
- Assistance in performing venipuncture to obtain access to central vein

Biocompatibility:
The materials used to manufacture the Multi-Snare Set comply with the requirements of ISO 10993-1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 4 2002

Mr. Salvadore F. Palomares
Regulatory Consultant for pfm
PFM Produkte Fur Die Medizen AG
C/O Salvadore F. Palomares, RAC
15 Cherokee Streeet
Trabuco Canyon, CA 92679

Re: K011783
Trade Name: Multi-Snare Ser
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: II
Product Code: 74 MMX
Dated: January 17, 2002
Received: January 18, 2002

Dear Mr. Palomares:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

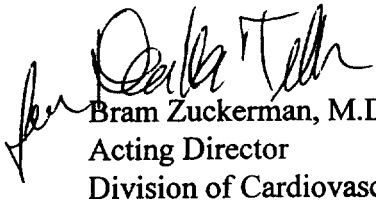
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k): **K011783**

Device Name: **Multi-Snare Set**

Indications for Use: The Multi-Snare Set (and its components) is intended for:
Retrieval and manipulation of foreign objects from the vascular system and hollow viscera
Assistance in creating loops where cross-over technique is applied
Repositioning of indwelling venous catheters
Assistance in performing venipuncture to obtain access to central vein

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or _____ Over the Counter Use
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices

510(K)
NUMBER K011783

Division of Cardiovascular & Respiratory Devices
510(k) Number K011783